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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,285	03/02/2005	Nitin Bhalachandra Dharmadhikari	006420.00004	4683

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EXAMINER	
GRAFFEO, MICHEL	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/526,285	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,23,24,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,23,24,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 Mar 06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1-18, 23-24 and 27-28 are examined.

Applicant has amended claims 1-2, 5, 8, 9-18 and 24, added new claims 27-28 and provided arguments for the patentability of claims 1-18, 23-24 and 27-28 in the response filed 2 March 2006.

Applicant's arguments, see response, filed 2 March 2006, have been fully considered and are persuasive to the extent of the rejections under 35 USC §112. Therefore, the previous rejection of claims 5 and 8-15 under 35 USC §112, have been withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18, 23-24 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 1-18 and 23-24 the Specification does not reasonably convey to one skilled in the art that the inventor(s) had possession of a pharmaceutical composition having enhanced oral bioavailability as compared to the conventional pharmaceutical composition of metaxalone when administered without food to a patient who has fasted. Although the Examiner notes the Example on pages 9-10 which describes a situation wherein patients were dosed with metaxalone after an overnight absence of food, the Specification does not sufficiently describe the increased bioavailability of a metaxalone formulation wherein patients are fasting for any particular time period or fasting for an unlimited time period.

Regarding claim 28, a claim directed to a composition wherein the bioavailability is characterized in relationship to an NDA is not in the instant Specification.

Claim Rejections - 35 USC § 102

Claims 1-2 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,407,128 to Scaife et al.

Scaife et al. teach a pharmaceutical composition comprising a 400mg tablet, inclusive of excipients, (in current claims 1-2 and 15; see col 1 lines 28-29) of metaxalone (in current claims 1-2 and 15; see Treatment A in col 3 lines 14-15) having an enhanced oral bioavailibility and necessary increased solubility in that it is dosed with

food (in current claims 1-2 and 15; see Title and Abstract). Examiner further notes that the phrase "when administered without food" claim 1 is interpreted to characterize the commercially available metaxalone which is being compared to the pharmaceutical composition of the instant invention.

Claim Rejections - 35 USC § 103

Claims 1-15 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,407,128 to Scaife et al. in view of US Patent No. 6,030,988 to Gilis et al.

Scaife et al. teach a pharmaceutical composition comprising a 400mg tablet, inclusive of excipients, (in current claims 1-2 and 15; see col 1 lines 28-29) of metaxalone (in current claims 1-2 and 15; see Treatment A in col 3 lines 14-15) having an enhanced oral bioavailibility and necessary increased solubility in that it is dosed with food (in current claims 1-2 and 15; see Title and Abstract).

Scaife et al. do not teach any particular values for the size of the metaxalone particles in the dosage form nor name any particular solubilizing agent such as monoglyceride for example.

Gilis et al. teach a micronized formulation of cisapride, inclusive of a solubilizing agent such as monoglycerides (in current claim 7; see col 9 line 45) wherein at most 50% of the particles may have a diameter larger than 24 μm which allows for particle sizes of 40 μm, 30 μm and 10 μm (in current claims 8,11-14; see col 5 lines 45-50) and a surface area per unit volume of more than $14x10^3$ m^2/kg, which when compared

based on a 1cc=1g (for water) basis equates to an amount more than1400 m^2/kg and since the particle size ranges in the reference are the same as in the instant claims the ranges for the surface area unit volume must also be the same (in current claims 9-11; see col 5 lines 39-45).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Scaife et al. with Gilis et al. since Scaife et al. cites Gilis et al. on the front page of the Scaife et al. patent. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,407,128 to Scaife et al. as applied to claims 1-15 above in view of US Patent No. 6,099,859 to Cheng et al.

Scaife et al. do not teach a pharmaceutical comprising a wetting agent such as sodium lauryl sulfate.

Cheng et al. teach a pharmaceutical comprising sodium lauryl sulfate (in current claims 16-18; see col 7 lines 35-40 in Example 2).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Scaife et al. with Cheng et al. since Scaife et al. cites Cheng et al. on the font page of the patent. Thus, the combined

references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,407,128 to Scaife et al. as applied to claims 1-15 above.

Although Scaife et al. do not particularly recite a pharmaceutical composition comprising metaxalone and another analgesic, combining agents which are known to be useful as aalgesics individually into a singe composition useful for the very same purpose is prima facie obvious. See In re Kerkhoven 205 USPQ 1069.

Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining analgesics flows logically from their having been individually taught in the prior art.

Response to Arguments - 35 USC § 102

Applicant's arguments filed 2 March 2006 have been fully considered but they are not persuasive. As Applicant points out, the Specification compares a micronized metaxalone composition with that of a commercially available metaxalone composition. To the extent of the scope of claim 1 which includes micronized metaxalone, Sciafe et al. does not anticipate the claim. Nonetheless, the scope of claim 1 is broader than a composition comprising micronized metaxalone. Moreover, as amended claim 1, for example, claims a metaxalone formulation which has enhanced bioavailability as

compared to a commercially available formulation when the commercially available formulation is taken without food. The limitation in claim 1 does not exclude a formulation which has enhanced bioavailability as compared to a commercially available formulation when the commercially available formulation is taken with food. The later is that which is taught by Sciafe et al. in col 2 lines 16-23:

> One aspect of this invention is a method of increasing the bioavailability of metaxalone in a human patient receiving metaxalone therapy wherein the metaxalone is contained in a pharmaceutical composition, which method comprises administering a therapeutically effective amount of metaxalone to the patient with food.

Response to Arguments - 35 USC § 103

Applicant's arguments filed 2 March 2006 have been fully considered but they are not persuasive. Applicant points out that Gilles et al. does not teach a formulation of metaxalone. That notwithstanding, Gilles et al. teach that bioavailability of any agent is affected by a number of factors (see col 1 lines 15-20):

> In general, it is known that the absorption and bioavailability of any particular therapeutic agent can be affected by numerous factors when dosed orally. Such factors include the presence of food in the gastrointestinal (GI) tract because, in general, the gastric residence time of a drug is usually significantly longer in the presence of food than in the fasted state. If the bioavailability of a drug is affected

Gilles et al. further teach a micronized formulation of cisapride which in light of the teachings above as a motivating factor to micronize a formulation for bioavailability

makes obvious the instant claims. Additionally, that one reference is sited by another is a sufficient motivating factor to combine the references.

Applicants contend that the reliance on Cheng et al. is not proper. Cheng et al. is sited by Scaife et al. and therefore properly combined. Further, Cheng et al. teach a formulation comprising sodium lauryl sulfate as a surfactant. Sodium lauryl sulfate is a common surfactant used as a detergent, wetting agent, and food additive. (see sodium lauryl sulfate. Academic Press Dictionary of Science and Technology (1992). Retrieved 22 May 2006, from xreferplus. http://www.xreferplus.com/entry/3159939). To that extent, one of ordinary skill in the art would have had in their possession all the limitations to the claimed invention and a proper motivation to combine all the limitations of the instant claims.

Conclusion

No claim is allowed.

Applicant's amendment, specifically the addition of claim 28, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5 June 2006
MG

Ardin H. Marschel 6/11/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER